Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Withdrawn) A method for the administration of an injectable formulation into the epidermal, dermal or subcutaneous layer of an animal to effect pain-free or substantially pain-free administration of a therapeutic agent, comprising injecting from about 0.1 to about 10 microliters of an ultraconcentrated semisolid or solid formulation comprising from about 20 to about 85% solids by weight and comprising an effective amount of a therapeutic agent into the epidermal or dermal skin layer of an animal.

2. (Withdrawn) The method of claim 1, wherein a powdered form of the therapeutic agent is surrounded by a liquid to form a slurry or a paste.

3. (Withdrawn) The method of claim 1, further comprising processing the therapeutic agent in order to decrease its particle size to a mean particle size range from 10 nanometers (0.01 microns) to about 100 microns, with no particles being larger than about 500 microns.

4. (Withdrawn) The method of claim 3, wherein the mean particle size of the therapeutic agent is reduced to a mean particle size from about 0.1 microns to about 25 microns, with no particles being larger than about 50 microns.

5. (Withdrawn) The method of claim 3, wherein the mean particle size of the therapeutic agent is from about 1 to about 10 microns.

6. (Withdrawn) The method of claim 1, wherein the therapeutic agent is incorporated into a non-aqueous or semi-aqueous pharmaceutically acceptable carrier.

7. (Withdrawn) The method of claim 6, further comprising incorporating a polymer into the carrier such that said formulation exhibits thixotropic properties upon injection from an injection device.

8. (Withdrawn) The method of claim 1, further comprising incorporating the semisolid formulation into the needle of an injection device comprising a needle suitable for intradermal injection and a biasing device causing said needle to penetrate the skin of an animal and forcing the formulation out of the needle upon activation of said device.

9. (Withdrawn) The method of claim 8, further comprising incorporating a plunger into the device, said biasing device forcing said plunger against said formulation and forcing substantially all of said formulation out of said needle upon activation of said device.

10. (Withdrawn) The method of claim 8, further comprising incorporating a retraction device into said injection device which is activated after the injection is made in order to retract the empty needle.

11. (Withdrawn) The method of claim 10, further comprising incorporating a skin positioner onto the injection device, such that when said injection device is set against the skin of an animal to be injected, the skin positioner stretches the skin in order to reduce pain caused by the penetration of the needle into the skin of the animal upon activation of the injection device and allows for shallow injection.

12. (Withdrawn) The method of claim 11, further comprising incorporating said needle within a housing of said injection device, such that the needle extends from said housing only when said injection device is actuated during use.

13. (Withdrawn) The method of claim 10, further comprising manufacturing the skin positioner from soft rubber, and attaching said skin positioner to the end of said housing of said injection device.

14. (Withdrawn) The method of claim 9, further comprising preparing said plunger as a deformable gel, and loading said gel into the upper portion of said needle, such that upon activation, said gel forces said formulation through the tip of the needle.

15. (Withdrawn) The method of claim 8, further comprising providing said needle with an expandable tip, such that said needle has a substantially flat orientation prior to use when containing said formulation, and such that said tip expands as said formulation is forced through it, thereby allowing the therapeutic formulation to flow out of the needle tip.

16. (Withdrawn) The method of claim 1, further comprising spray drying said therapeutic agent, and thereafter incorporating said agent into a pharmaceutically acceptable carrier to form a slurry or paste.

17. (Withdrawn) The method of claim 1, further comprising lyophilizing said therapeutic agent, and thereafter incorporating said agent into a pharmaceutically acceptable carrier to form a slurry or paste.

18. (Withdrawn) The method of claim 17, further comprising performing the lyophilization at least partially above the glass transition temperature (Tg) of the therapeutic agent formulation to induce a collapse of the mass to form a dense cake.

19. -35. (Cancelled)

36. (Withdrawn) A device for injection of a therapeutic agent into the epidermal or dermal layer of the skin of an animal which effects pain-free or substantially pain-free administration of a therapeutic agent, comprising

a needle suitable for intradermal injection, said needle having a lower end containing a unit dose of a therapeutic agent homogeneously contained within a slurry or paste; and a biasing device arranged at an upper end of said needle;

said needle and said biasing device being contained within a housing, said housing including an activator, such that when said injection device is set against the skin of an

animal, said activator can be activated to release said biasing device, thereby causing said needle to penetrate the skin of an animal and forcing substantially all of said unit dose out of a tip located at the lower end of said needle.

37. (Withdrawn) The device of claim 36, further comprising a plunger disposed against an upper end of said unit dose contained within said needle, said biasing device forcing said plunger against said formulation and forcing substantially all of said formulation out of said lower tip of said needle upon activation of said device.

38. (Withdrawn) The device of claim 36, wherein said needle is at least about 5 cm in length, and is from about 27 to about 30 gauge.

39. (Withdrawn) The device of claim 36, wherein said injection device further comprises a retraction device contained within said housing, said retraction device being activated after the injection is made in order to pull back the empty needle.

40. (Withdrawn) The device of claim 36, further comprising a skin positioner attached to the lower end of said housing, said skin positioner being capable of stretching the skin of an animal when said injection device is set against the skin of an animal to be injected, in order to reduce pain caused by the penetration of the needle into the skin of the animal upon activation of the injection device.

41. (Withdrawn) The device of claim 36, wherein said needle is disposed within said housing of said injection device such that said needle extends from said lower end of said housing only when said injection device is actuated during use.

42. (Withdrawn) The device of claim 40, wherein said skin positioner is made of a soft rubber.

43. (Withdrawn) The device of claim 37, wherein said plunger is a deformable gel, said gel being arranged in an upper portion of said needle, such that upon activation, said gel forces said formulation through said lower rip of said needle.

44. (Withdrawn) The device of claim 36, wherein the lower tip of said needle has a substantially flat orientation prior to use when containing said unit dose such that a peak is created for puncturing the skin, said tip being capable of expanding as said formulation is forced through it during use, thereby allowing the formulation to flow out of the needle tip.

45. (Withdrawn) The device of claim 37, wherein said plunger is a metal wire.

46. (Withdrawn) The device of claim 37, which achieves substantially 100% displacement of the dose out of the injection needle during use.

47. (Withdrawn) The device of claim 36, wherein the extreme tip of the needle is crimped into a flat orientation to create a peak by which to puncture the skin.

48. (Withdrawn) The device of claim 36, wherein multiple needle systems are contained within said housing, such that multiple penetrations are made to the skin during use, simultaneously dosing a larger dose of said therapeutic agent while maintaining small individual volumetric injections.

49. (Withdrawn) The device of claim 36, wherein an upper portion of the needle is widened in a smooth manner relative to the lower tip of the needle, in order to hold up to about 1.5 ml of said therapeutic formulation.

50. (Withdrawn) The device of claim 39, wherein said biasing device is a spring which is released upon activation of the injection device, and said retraction device is a spring which is activated after the injection is made in order to pull back the empty needle.

51. (Withdrawn) The device of claim 36, further comprising a dose controller arranged on said housing which can be adjusted to change the distance that the plunger travels through the needle, thereby controlling the amount of therapeutic formulation forced through the needle rip and thereby changing the dose administered to a patient during use.

52. (Withdrawn) The device of claim 36, wherein said biasing device is a pressure source.

53. (Withdrawn) The device of claim 52, wherein said pressure source comprises a gas source.

54. (Withdrawn) The device of claim 52, wherein said pressure source comprises a piston.

55. (Withdrawn) The device of claim 39, wherein said retraction device comprises a pressure source selected from a gas source and a piston.

56. (Withdrawn) The device of claim 36, wherein the unit dose comprises a dry powder formulated without a liquid carrier and the inner surface of the needle is coated with a lubricant to allow particle flow.

57. (Withdrawn) A method for the administration of an injectable formulation into the epidermal, dermal or subcutaneous layer of an animal to effect pain-free or substantially pain-free administration of a therapeutic agent, comprising incorporating from about 0.1 to about 10 microliters of an ultraconcentrated dry particulate formulation comprising an effective amount of a therapeutic agent and a pharmaceutically acceptable carrier into the needle of an injection device comprising a housing containing a needle suitable for intradermal injection, an actuator, and a biasing device; coating the inner surface of the needle with a suitable lubricant prior to incorporation of the formulation into the needle to allow particle flow of the formulation out of the needle in use; positioning the housing against the skin of an animal, actuating the actuator such that the biasing device is released and causes the needle to penetrate the skin of an animal and forces the formulation out of the needle.

58. (Withdrawn) The method of claim 57, wherein the formulation is injected into the epidermal or dermal skin layer of an animal.

59. (Withdrawn) The method claim 57, wherein the formulation is coated with a lubricant to allow flow down the lumen of the needle.

60. (New) A composition for intracutaneous injection of a therapeutic agent, said composition comprising about 0.1 to about 10 microliters of an ultraconcentrated semisolid, said ultraconcentrated semisolid comprising an effective amount of said therapeutic agent homogeneously contained within a pharmaceutically acceptable carrier, wherein said ultraconcentrated semisolid comprises from about 20 to about 85% solids by weight and is in the form of a paste suitable for intracutaneous injection.

61. (New) The composition of claim 60, wherein said therapeutic agent has a mean particle size ranging from 10 nanometers (0.01 microns) to about 100 microns, with no particles being larger than about 500 microns.

62. (New) The composition of claim 60, wherein said therapeutic agent has a mean particle size ranging from about 0.1 microns to about 25 microns, with no particles being larger than about 50 microns.

63. (New) The composition of claim 60, wherein said therapeutic agent has a mean particle size ranging from about 1 to about 10 microns.

64. (New) The composition of claim 60, wherein said ultraconcentrated semisolid further comprises a polymer that imparts thixotropic properties to said composition.

65. (New) The composition of claim 60, wherein said ultraconcentrated semisolid comprises from about 50% to about 80% solids by weight.

66. (New) The composition of claim 19, further comprising an effective amount of a stabilizing agent.

67. (New) The composition of claim 28, wherein said stabilizing agent is a member selected from the group consisting of surfactants, polyoxamers, polyols, gels, amphoteric compounds, and mixtures thereof.

68. (New) The composition of claim 60, wherein said composition is stable against unacceptable levels of aggregation, oxidation and hydrolysis related degradation pathways for at least about 2 months when said composition is stored at an elevated temperature of 37° C.

69. (New) The composition of claim 60, wherein said pharmaceutically acceptable carrier is a non-aqueous or semi-aqueous carrier.

70. (New) The composition of claim 60, wherein said pharmaceutically acceptable carrier is a non-aqueous carrier.

71. (New) The composition of claim 60, wherein said pharmaceutically acceptable carrier is selected from the group consisting of alkyl benzoates, aryl benzoates, aralkyl benzoates, triacetin, dimethyl sulfoxide (DMSO), N-methyl -2- pyrrolidone (NMP), and mixtures thereof.

72. (New) The composition of claim 60, wherein said pharmaceutically acceptable carrier is selected from the group consisting of triacetin, N-methyl-2-pyrrolidone (NMP) and benzyl benzoate.

73. (New) The composition of claim 60, wherein said therapeutic agent is subjected to lyophilization, spray-drying or freeze-drying prior to incorporation into said pharmaceutically acceptable carrier.

74. (New) The composition of claim 60, wherein said ultraconcentrated semisolid further comprises a pharmaceutically acceptable polymer in an amount effective to slow the release of said therapeutic agent from said composition upon intracutaneous injection.

75. (New) The composiiton of claim 60, wherein said therapeutic agent is incorporated into liposomes or conjugated to or incorporated with polysaccharides and/or other polymers to provide a controlled release of said therapeutic agent from said formulation upon intracutaneous injection.